

### **Response to Claim Rejections under 35 USC § 112**

The applicant believes that with the Examiners helpful suggestion(s) that he has overcome the Examiner's rejection to claims 23-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In addition, the Applicant has requested constructive assistance and if, for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. § 107.03(d) and § 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

In response to the rejection with regards to the appearance of the test strip as always positive and lack of clarity with regards to the wording of "means" the applicant has altered the claims to overcome the rejection.

The Applicant changed the Claim 27 to meet the Examiners requirement with reference to the "color" of the reaction and agrees that it further defines the claims. However, it would not be possible to add in all of the colors into claim 23 but, the applicant could add each specific color dependent upon which indicator substrate complex was used. With the Examiner's help I believe this could be accomplished with ease if necessary.

The Applicant will respond with an appropriate affidavit that support the method and how the assay was made.

### **Response to Claim Rejections under 35 USC § 103**

The newly amended, deleted, and added claims have overcome the Examiners rejection of claims 23-29 under 35 U.S.C. 103 and 35 U.S.C. 103(a) as being unpatentable over Fuerst et al. (US 6214970B1) and van de Perre et al. (J Clinical Microbio 1988 Vol 26, pages 552-556) and Fuerst et al. (US 6214970B1) and van de Perre et al. (J Clinical

Microbio 1988 Vol 26, pages 552-556) and Harlow and Lane (Antibodies A Laboratory Manual). Again, neither Fuerst or van de Perre teach the Applicants device, these reference which has absolutely nothing to do with the present art that they do not teach the Applicants device but can vaguely referenced because one talks about antibody detection (not HIV as noted by the Examiner) and the other talks about the need but provides no teaching and is in fact without any reference point to even relate to the present art. The applicant fails to find any reference in Fuerst or van de Perre claims or specification for the use of an aqueous reagent comprising a buffer, an indicator, and HIV antigen conjugated to an indicator substrate to detect HIV antibodies in a normalized urine sample in a chemistry analyzer, etc. It appears to the applicant that the Examiner has made a **strained interpretation** of the reference that could only be made by hindsight. As the Courts have stated, "It is impermissible to use the claimed invention as an instruction manual to "template" or piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that one cannot use hindsight construction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." in re Fritch supra, 1784.

The physical features of Smith are completely different (**novel**) from that of Fuerst, van de Perre, Harlow and Lane. The reference of the above **teach away** from the Smith in that Smith invention is liquid carrier free reagent that does not have all of the requirements of above.

The Examiner rejection to claims 23-29 as being unpatentable over Fuerst et al. (US 6214970B1) and van de Perre et al. (J Clinical Microbio 1988 Vol 26, pages 552-556) and Fuerst et al. (US 6214970B1) and van de Perre et al. (J Clinical Microbio 1988

Vol 26, pages 552-556) and Harlow and Lane (Antibodies A Laboratory Manual) under 35 U.S.C. § 103 should be reversed because the art cited by the Examiner does not teach applicant's limitations as claimed, i.e., carrier free reagent, no need for ELISA technology or other requirements and limitations, etc. The Courts have stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it."

The device of Smith uses a "**new principle of operation**" in that the use of normalizing urine, no need for polystyrene carrier, carrier free reagent, no washing, no ELISA technology, etc., and was not taught by the prior art and is absolutely novel in structure and function as compared to the prior art. The applicant's invention solves a different problem than the reference, and such differences are cited in the claims, such as no required pretreatment of specimens prior to analysis, no capturing of the antibody by a carrier to determine the presence of HIV antibodies. See *In re Wright*, 6 USPQ 2d 1959 (1988). The van de Perre only ask that it be done (e.g. would someone please invent it).

The Examiner should reverse the rejection of claims 23-29 under 35 U.S.C. § 103(a) as being unpatentable over Fuerst et al. (US 6214970B1) and van de Perre et al. (J Clinical Microbio 1988 Vol 26, pages 552-556) and Fuerst et al. (US 6214970B1) and van de Perre et al. (J Clinical Microbio 1988 Vol 26, pages 552-556) and Harlow and Lane (Antibodies A Laboratory Manual). Because applicant's newly amended, and newly added claims recite novel physical features (i.e., it clears § 102). The novel physical distinctions of claims 3, 5 and 7-9 and 11 are unobvious under § 103(a) for the following reasons. The present device produces **unexpected results** due to the inherent design and capability differences between the inventions. When the devices are juxtapose

the results produced are unexpected. The present device is an automated method for the analysis of HIV antibodies in urine or other fluids effectively allowing **superior** results with reference to time, cost, and accuracy. The Examiner has not presented a convincing line of reasoning as to why the claimed subject matter as a whole, including its differences over the prior art, would have been obvious. Nor does the prior art teach the present art of Smith. The applicant's invention **solves a different problem** (detection of HIV antibodies in urine using a carrier free reagent) that the reference cannot, and such a solution to the different problem is recited in the claims.

It appears to the applicant that the Examiner has made a **strained interpretation** of the reference that could only be made by hindsight. As the Courts have stated, "It is impermissible to use the claimed invention as an instruction manual to "template" or piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that one cannot use hindsight construction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." in re Fritch supra, 1784.

Thus the applicant submits that their invention clearly recites novel physical subject matter which distinguishes over any use of Fuerst, van de Perre, Harlow and Lane as a prior art or teaching.

**The Newly Amended Novel Physical features of Claims 23-29 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The Reference Under § 103.**

Again, Such hindsight reconstruction of an invention to support a rejection under 35 U.S.C. 103 is improper as clearly set forth by the Court of Appeals For the Federal

Circuit in *In re Fritch*, 23 USPQ 2d 1780 at 1783-1784 (CAFC 1992) where it is stated, "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination" ..... "Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This Court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures of the prior art to deprecate the claimed invention'."

For these reasons, the Examiner's rejection of newly amended claims 23-29 35 U.S.C. § 103 should be reversed.

The prior art does not teach the present art or solve any problems of the prior art then why the rejection? 35 U.S.C. 103 **does not require** all of the elements of the prior art to be used in combination. Therefore, and in fact, if the Examiner uses any combination of the prior art and still does not create the present art it in fact invalidates the Examiners argument.

That the suggestion to combine the references should not come from applicant was forcefully stated in Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193, 199 (CAFC 1983):

"It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims pending]. Monday morning

quarterbacking is quite improper when resolving the question of nonobviousness in a court of law [here the PTO]."

As was further stated in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q.2d 1434 (C.A.F.C. 1988), "[w]here prior-art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.... Something in the prior art must suggest the desirability and thus the obviousness of making the combination," [Emphasis supplied.]

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

"In order to establish a *prima facie* case of the obviousness, it is necessary for the examiner to present *evidence*, preferable in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied reference(s) in the proposed manner to arrive at the claimed invention. ...That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by mean of logic and sound scientific reasoning *does not* afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching

in either prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the relevant teachings of the references.' ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the *motivating force* which would impel one skilled in the art to do what the *applicant has done.*"

In the present case, there is no reason to support the use of Fuerst, van de Perre, Harlow and Lane as a teaching to establish obviousness when the extent of the teaching are at best only considered "**conceivable or possible**" by the prior art. This is not sufficient teaching to establish obviousness. However the fact that the reference teaches a device that is supposed to be used to remove interference using amino acids in the detection of HIV is not sufficient to **gratuitously and selectively** substitute parts of the reference and combined in a manner that was unsuggested by the prior art in order to attempt to meet applicants' novel claimed invention.

Applicant therefore submits that use of a method that is designed to remove interferences is not legally justified and is therefore improper. The applicant respectfully request that the claims 23-29 be reversed and if the Examiner continues to reject the claims upon any combination of references, that the Examiner include an explanation, in accordance with M.P.E.P. § 706.02, Ex parte Clapp, 27 U.S.P.Q. 972 (P.O.B.A. 1985), and Ex parte Levengood, supra, a "factual basis to support the Examiner's conclusion that it would have been obvious" to use Fuerst, van de Perre, Harlow and Lane as a prior art reference that is designed for a completely different use..

For these reasons, the Examiner's rejection of amended claims 23-29 under 35 U.S.C. § 103 should be reversed.



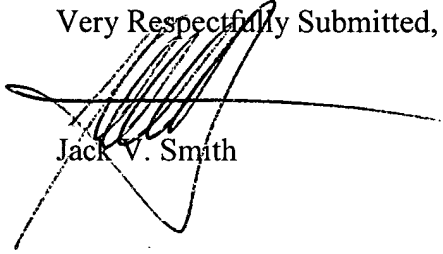
**Conclusion**

For all of the above reasons, applicant submits that the specification and properly limited claims are in proper form, and that the claims all define patentably and clearly. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

### Conditional Request For Constructive Assistance

Applicants have amended the specification and claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. § 107.03(d) and § 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully Submitted,



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signed



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